Remarks

1. Claims 21, 22, 27, 28, 33 and 44-47 have either been cancelled or amended to overcome the Examiners § 112 rejection.

2. The claims remaining in the application have been rejected under 35 U.S.C. 103(a) as anticipated by Schultz [US 6,256,522] in view of Krauth [US 4,954,435}, and/or Vo-Dinh [US 5,864,397]. Claim 1, as amended, claims a seamless device for detecting the presence of an analyte in a sample. The claim requires a core comprising of a binding substrate with an analyte binding site, an analogue that binds in the binding site and which has a label with a first emission wavelength, a quenching dye, a reference having emission wavelength different from label, and an analyte permeable membrane transparent to light of the wavelengths used to excite label and reference, wherein the binding substrate has molecular imprint of the analyte. None of the references either alone or in combination teach such a seamless sensor device.

The ability to construct seamless devices has many advantages, such as increased resistance to rupture due to mechanical stress, reduced risk of an immunological response, reduced irritation/inflammation post implantation, and ease of in vivo delivery.

Although Schultz illustrates the use of an implantable sensor capsule for measuring the concentration of certain bioanalytes in a patient, there is no mention of the sensor capsule being seamless in its construction. Infact, Schultz indicates that the sensor capsule may have two or more components joined mechanically by screwed joints with O-rings, or preferably sealed by adhesion or heat. Alternatively, the sensor capsule may be composed of a small hollow cylindrical device having one integral end. The other end could be sealed via a suitable membrane held in place via a retainer ring.

The other two references cited by the Examiner (Krauth et al., and Vo-Dinh et al.), disclose the use of multi-component external devices that can be used to detect concentration of an analyte.

One of ordinary skills in the art would not have any incentive to combine the teachings of Schultz (an implantable device) with that of Krauth and Vo-Dinh (an externally placed device). Even if such references were to be combined they still would not teach a seamless device for detecting the presence of an analyte.

Furthermore, claim 1 as amended, requires that the binding substrate has a molecular imprint of the analyte of interest. As the examiner correctly points out, Schultz teaches a binding substrate encompassed within a sensor capsule, but fails to teach that the binding substrate has a molecular imprint of the analyte.

Krauth teaches detection of an analyte through an enzyme immunoassay by indirect colorimetric detection. An incident light beam at a plurality of wavelengths is directed into a solution of the analyte. The solution is capable of attenuating, by absorption, the amount of light at the first wavelength scattered from said incident beam, as a function of increasing analyte concentration. A light signal from the solution at the first wavelength is detected, and light at a second wavelength spectrally removed from the first, and which is not substantially attenuated by increasing concentration of analyte is also detected. A ratio of signal intensity at the two wavelengths is calculated and compared with ratios of signal intensities obtained from samples having known concentration of said analyte, to determine the concentrattion of analyte in the sample.

Vo-Dinh teaches an external probe that includes a member made of optically transmissive material for detecting analyte via Surface-Enhanced Raman Scattering Spectroscopy when placed in contact with it. The end of the member is made of a microparticulate first layer overlayed with a metal layer for enhancing the Raman signals. An optional layer having a molecular imprint of the analyte of interest may be applied to the metal layer to concentrate analyte of interest.

Unlike the invention of claim 1, neither Vo-Dinh nor Krauth contain an analyte permeable membrane encapsulating the core sensor elements and reference. In fact, none of the references disclose a seamless device with a molecular imprint for detecting concentration of a

particular analyte of interest. Furthermore, one of ordinary skills in the art could not combine the cited references to produce the invention of claim 1.

For all of the reasons cited above, it is clear the none of the references suggest or disclose the device of this invention. Furthermore, there is no motivation to combine these references, and that even if combined, they do not disclose or suggest the device of the present invention. Claim 1 is therefore patentable over the prior art.

3. Claims 2-47 depend from or otherwise incorporate all the limitations of claim 1. As such they are patentable for at least the same reasons as claim 1.

In view of the foregoing amendments and remarks, it is respectfully submitted that the application is in condition for allowance and Applicants earnestly solicit early examination on the merits and issuance of a Notice of Allowance. Should the examiner believe that any additional information or amendment is necessary to place the application in condition for allowance, he is urged to contact the undersigned Attorney via telephone at 617-439-2746/ 617-439-2672, or facsimile number 617-310-9746/617-310-9672.

The Commissioner is hereby authorized to charge any required fees due in connection with this submission, including petition and extension of time fees, and to credit any overpayment to Deposit Account No. 141449 (Docket No. 106570-0002) (LifeScan Inc.).

Respectfully submitted,

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